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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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John D. Nguyen

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EXAMINER

WOO, JULIAN W

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/718,236	Applicant(s) NGUYEN ET AL.	
	Examiner Julian W. Woo	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18, 21, 24, 25, 27 and 29 is/are allowed.
- 6) ☒ Claim(s) 17, 19, 20, 22, 26 and 28 is/are rejected.
- 7) ☒ Claim(s) 23 and 30-33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
2. Claims 17, 19, 20, 22, 26, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Northrup (5,972,024) in view of Pyka et al. (5,002,563), and further in view of Krajicek (5,413,597). Northrup discloses the invention substantially as claimed. Northrup discloses, at least in figures 4-9 and col. 4, lines 5-54; a clip assembly and a method of holding two tissue parts together, where the assembly and method include two clips (60) each having two end points, a proximal end point and a distal end point, the proximal end point and the distal end point being separated from each other when the clip is held in an open configuration; two tissue penetrating needles (40) each releasably connected to one of the two end points (see also col. 4, lines 61-65, where the needles (and sutures) may be cut from, i.e., released from the clips), and a

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“structure” (e.g., 310 in fig. 9) connecting the other end points of the two clips together; where the method includes penetrating and completely pulling one of the needles through a tissue part (e.g., 320 in fig. 9) and penetrating and completely pulling the other of the needles through an adjacent tissue part (e.g., also at 320) while the clips are each in an open configuration; pulling the needles until each of the clips is hooked to a corresponding one of the tissue parts, and where the two tissue parts are held together by the flexible connector stretched between the clips. However, Northrup does not disclose that the clip has a tendency to return to a naturally closed configuration and is formed of a wire made of shape memory material. Northrup also does not specifically disclose that the clips each include a stopper connected to one of the two end points of the clip. Northrup does not disclose that the “structure” is a flexible connector, where the flexible connector forms a loop when stretched between the clips.

Pyka et al. teach, at least in figures 5A-6B2 and col. 4, lines 26-58; a clip having a tendency to return to a naturally closed configuration from an open configuration, where the clip is formed of a wire made of shape memory material. It would have been obvious to one having ordinary skill in the art at the time the invention was made, to apply a clip as taught by Pyka et al. in the device and method of Northrup. Such a clip would help draw tissue parts together and join them without requiring the extra time for crimping of the clip.

Northrup further discloses in figures 10-12 and col. 5, lines 39-51, a clip (460) applicable to the abovementioned clip assembly, where the clip includes a stopper (490) connected to one of the two end points of the clip. It would have been obvious to one

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having ordinary skill in the art at the time the invention was made, to apply clip 460 in the clip assembly. Such a clip with a stopper, such as element 490, would serve to anchor the clip more securely against a tissue structure.

Additionally, Krajicek teaches, at least in figure 1 and in col. 1, line 62 to col. 2, line 14; an flexible connector usable for the anastomosis as disclosed by Northrup or Northrup in view of Pyka et al. The flexible connector of Krajicek forms a loop, i.e., elements 1, 2, and/or 3 form a circumferential structure at the end of the connector. It would have been obvious to one having ordinary skill in the art to apply a flexible connector, in view of Krajicek, in the apparatus and method of Northrup or Northrup in view of Pyka et al. Such a connector would be useful for replacing or repairing a defective vascular structure, and it would effectively prevent leakage around the clips when the connector and clips are joined to another vascular structure.

Allowable Subject Matter

3. Claims 18, 21, 24, 25, 27 and 29 are allowed.
4. The following is an examiner's statement of reasons for allowance: None of the prior art of record, alone or in combination, discloses a clip assembly and a method with the clip assembly for holding two tissue parts together, where the assembly and method include, inter alia, two clips, each clip having an open configuration and tending to return to a naturally closed configuration; two tissue penetrating needles connected to the clips via flexible members, and a flexible connector connecting the clips, where the clip assembly has a releasing means for normally keeping the two clips in the open

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configuration and releasing the clips to become separated from the flexible members and allowing the clips to return to the closed configuration.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

5. Claim 23 and 30-33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a clip assembly including, inter alia, two clips, each clip having an open configuration and tending to return to a naturally closed configuration; two tissue penetrating needles connected to the clips via flexible members, and a flexible connector connecting the clips, where the clip assembly has a releasing means for normally keeping the two clips in the open configuration and releasing the clips to become separated from the flexible members and allowing the clips to return to the closed configuration, and where the flexible connector is a suture or metal wire.

.As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Response to Amendment

7. Applicant's arguments filed on February 27, 2009 have been fully considered but they are not fully persuasive. That is, with respect to arguments regarding the rejection of claims 17 and 20 and based on Northrup: The Examiner agrees with Applicant in that a blood vessel cannot be a "flexible connector." Nonetheless, Northrup discloses a "structure" (e.g., 310) connecting end points of two clips together. This structure, as modified with the teachings of Krajicek, is indeed a "flexible connector" connecting end points of two clips together. In other words, when the clips are directly attached to a prosthesis as taught by Krajicek, a circumferential portion of the artificial structure connects the two clips. The ends of the clips are connected by virtue of the attachment of both clips to the blood vessel prosthesis.

The Examiner notes that claims 27 and 29 are allowable. The inclusion of these claims in the rejection was inadvertent.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773